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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,035	10/12/2000	Linda Gillian Durrant	0380-P02284U	5601

7590 03/14/2003

Dann Dorfman Herrell & Skillman
Suite 720
1601 Market Street
Philadelphia, PA 19103-2307

EXAMINER	
YU, MISOOK	14

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/623,035	DURRANT ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-7,11-14,19 and 34* is/are pending in the application.

4a) Of the above claim(s) *13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-7,11,12,19 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence alignment* .

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

DETAILED ACTION

Election/Restrictions

The prosecution history indicates that claims drawn to proteins and nucleic acids are separated as different invention groups (Groups I and II in Paper No. 8) because the special technical features in the original first claim do not contribute over prior art. Applicant argues that the protein sequence instant claim 1 was unknown before filing date of the instant application and requests rejoining of groups I and II because the instant claim 1 recite a specific protein. However, the prior art search reveals that the instant claim 1 does not contribute over the prior art, either. See art rejection below. Therefore the request for rejoining is denied. Since the protein sequence is the special technical feature and the special technical feature in the first claim does not contribute over art, unity between a protein and corresponding nucleic acid lacks unity.

Claims 1, 5-7, 11-14, 19, and 34 are pending and claims **13 and 14 remain withdrawn** for reason of record and also for the reason given above from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1, 5-7, 11-12, 19, and 34 are examined on merits.

Claim Rejections - 35 USC § 112

Claim 19 remain rejected for reason of record under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 19 is drawn to method of cancer treatment and cancer treatment is not a trial matter as stated at Paragraph #12 of the previous Office action (Paper No. 8). Applicant argues that since the instant claims are drawn to narrower scope of the protein in instant claim 1, fragments, or derivative thereof, the enablement rejection should be withdrawn. Considering the state

of art and the teaching of the specification, it is maintained that one skilled in the art would have reasons to question the efficacy of the claimed treatment method. In the absence of working example or other evidence of the method's effectiveness, it is maintained that undue experimentation would be required to practice the invention as claimed.

Rejection of claims 4-7, 9, 27, and 30-32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is moot** since the claims no longer refer to figures.

Rejection of the claims under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention is withdrawn since the instant claims no longer recite family of proteins.

NEW GROUNDS OF REJECTIONS

Claim Objections

The instant claims contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. 37 CFR 1.821(a) presents a definition for "nucleotide and/or amino acid sequences." The instant application contains an unbranched specifically defined sequence of more than ten nucleotides. Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. "Specifically defined" means

those amino acids other than "Xaa" and those nucleotide bases other than "n" defined in accordance with the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (1998), including Tables 1 through 6 in Appendix 2 (see MPEP § 2422). Amending the claims by referring to SEQ ID numbers would obviate this objection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 5-7, 11, 12, and 34 rejected under 35 U.S.C. 102(b) as being anticipated by WO 89/01041 (02-09-1989).

The claims are interpreted as reading on the composition *per se* and WO 89/01041 teaches protein that are 100 % identical to the protein in instant claim 1. Note the attached sequence alignment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
March 10, 2003

SHEELA HUFF
PRIMARY EXAMINER

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XX
PT   New decay accelerating factor variants - obtained with the factor by
PT   using recombinant DNA procedures.
XX
PS   Disclosure; Page 15-17; 20pp; English.
XX
CC   The probable phosphatidylinositol derivatisation site is Cys(330).
CC   The DAF variant is useful for treating paraoxysmal nocturnal
CC   haemoglobinuria, or inflammatory or cell lytic autoimmune
CC   diseases.  It may be used to ameliorate allograft rejection
CC   or autoimmune diseases. See also AAN70046, AAN70048.
CC   (Updated on 03-OCT-2002 to add missing OS field.)
XX
SQ   Sequence   381 AA;

  Query Match          100.0%;  Score 381;  DB 8;  Length 381;
  Best Local Similarity   100.0%;  Pred. No. 0;
  Matches  381;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy       1 MTVARPSVPAALPLLGELPRLLLLVLLCLPAVWGDCGLPPDVPNAQPALEGRTSFPEDTV 60
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1 MTVARPSVPAALPLLGELPRLLLLVLLCLPAVWGDCGLPPDVPNAQPALEGRTSFPEDTV 60

Qy      61 ITYKCEESFVKIPGEKDSVICLKGSQWSDIEEFCNRSCEVPTRLNSASLKQPYITQNYFP 120
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      61 ITYKCEESFVKIPGEKDSVICLKGSQWSDIEEFCNRSCEVPTRLNSASLKQPYITQNYFP 120

Qy     121 VGTVVEYECRPGYRREPSLSPKLTCLQNLKWSTAVEFCKKKSCPNPGEIRNGQIDVPGGI 180
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     121 VGTVVEYECRPGYRREPSLSPKLTCLQNLKWSTAVEFCKKKSCPNPGEIRNGQIDVPGGI 180

Qy     181 LFGATISFSCNTGYKLFGSTSSFCLISGSSVQWSDPLPECREIYCPAPPQIDNGIIQGER 240
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     181 LFGATISFSCNTGYKLFGSTSSFCLISGSSVQWSDPLPECREIYCPAPPQIDNGIIQGER 240

Qy     241 DHYGYRQSVTYACNKGFTMIGEHSIYCTVNNDEGEWSGPPPECRGKSLTSKVPPTVQKPT 300
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     241 DHYGYRQSVTYACNKGFTMIGEHSIYCTVNNDEGEWSGPPPECRGKSLTSKVPPTVQKPT 300

Qy     301 TVNVPTTEVSPTSQKTTTKTTTPNAQATRSTPVSRTTKHFHETTPNKGSGTTSGTTRLLS 360
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     301 TVNVPTTEVSPTSQKTTTKTTTPNAQATRSTPVSRTTKHFHETTPNKGSGTTSGTTRLLS 360

Qy     361 GHTCFTLTGLLGTLVTMGLLT 381
          |||||||||||||||||||||
Db     361 GHTCFTLTGLLGTLVTMGLLT 381


RESULT 2
AAP94773
ID   AAP94773 standard; protein; 381 AA.
XX
AC   AAP94773;
XX
DT   04-JUL-1990  (first entry)
XX
DE   Decay accelerating factor (DAF) of clones lambda 33 and lambda 47.
XX
KW   DAF; allograft rejection; affinity purification;
KW   autoimmune disease; ds.
XX
OS   Synthetic.
XX
PN   WO8901041-A.
XX
PD   09-FEB-1989.
XX
PF   03-AUG-1988;   88WO-US02648.
XX
PR   06-AUG-1987;   87US-0083757.
XX
PA   (GETH ) GENETECH INC.
XX
PI   Caras I;
XX
DR   WPI; 1989-061177/08.
DR   N-PSDB; AAN91043.
XX
PT   Fusion polypeptide for targeting protein to cell membrane -
PT   comprisesphospholipid anchor domain with heterologous
PT   polypeptide.
XX
PS   Disclosure; ; 61pp; English.
XX
CC   Recombinant DAF's are useful in treatment of inflamatory or cell lytic
CC   autoimmune diseases and allograft rejection. Useful in diagnostic
CC   compositions or in affinity purification.
XX
SQ   Sequence   381 AA;

  Query Match          100.0%;  Score 381;  DB 10;  Length 381;
  Best Local Similarity   100.0%;  Pred. No. 0;
  Matches  381;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy       1 MTVARPSVPAALPLLGELPRLLLLVLLCLPAVWGDCGLPPDVPNAQPALEGRTSFPEDTV 60
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1 MTVARPSVPAALPLLGELPRLLLLVLLCLPAVWGDCGLPPDVPNAQPALEGRTSFPEDTV 60

Qy      61 ITYKCEESFVKIPGEKDSVICLKGSQWSDIEEFCNRSCEVPTRLNSASLKQPYITQNYFP 120
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      61 ITYKCEESFVKIPGEKDSVICLKGSQWSDIEEFCNRSCEVPTRLNSASLKQPYITQNYFP 120

Qy     121 VGTVVEYECRPGYRREPSLSPKLTCLQNLKWSTAVEFCKKKSCPNPGEIRNGQIDVPGGI 180
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     121 VGTVVEYECRPGYRREPSLSPKLTCLQNLKWSTAVEFCKKKSCPNPGEIRNGQIDVPGGI 180

Qy     181 LFGATISFSCNTGYKLFGSTSSFCLISGSSVQWSDPLPECREIYCPAPPQIDNGIIQGER 240
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     181 LFGATISFSCNTGYKLFGSTSSFCLISGSSVQWSDPLPECREIYCPAPPQIDNGIIQGER 240

Qy     241 DHYGYRQSVTYACNKGFTMIGEHSIYCTVNNDEGEWSGPPPECRGKSLTSKVPPTVQKPT 300
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     241 DHYGYRQSVTYACNKGFTMIGEHSIYCTVNNDEGEWSGPPPECRGKSLTSKVPPTVQKPT 300

Qy     301 TVNVPTTEVSPTSQKTTTKTTTPNAQATRSTPVSRTTKHFHETTPNKGSGTTSGTTRLLS 360
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     301 TVNVPTTEVSPTSQKTTTKTTTPNAQATRSTPVSRTTKHFHETTPNKGSGTTSGTTRLLS 360

Qy     361 GHTCFTLTGLLGTLVTMGLLT 381
          |||||||||||||||||||||
Db     361 GHTCFTLTGLLGTLVTMGLLT 381


RESULT 3
AAR66683
ID   AAR66683 standard; Protein; 381 AA.
XX
AC   AAR66683;
XX
DT   23-JUL-1995  (first entry)
XX
DE   Decay accelerating factor.
XX
KW   Decay accelerating factor; DAF; mDAF; fusion protein; liposome;
KW   cell targeting; glycophosphatidylinositol; GPI; drug delivery.
XX
OS   Homo sapiens.
XX
FH   Key             Location/Qualifiers
FT   Peptide          1..34
FT                    /label= Sig_peptide
FT   Modified-site    364
FT                    /note= "probable phosphatidylinositol
FT                          derivatization site"
XX
PN   US5374548-A.
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